

REMARKS

Claims 19-22, 28-29, 32-40, 43-44, 47-55, 58-59 and 62-65 are pending.

1. Substance of March 9, 2006 Examiner Interview:

Applicant wishes to thank Examiner for the helpful suggestions proffered during the Interview. The substance of the Interview is described below.

While no explicit agreement was reached, there was a differentiation between structural and functional limitations relative to the claims. There was discussion surrounding the structural nature of the claimed invention and that, should Applicant amend the claims according to the parameters defining the structure of the present invention, such amendments may provide a better description of the present invention. Furthermore, amending the claims to provide a better structural depiction of the present invention may obviate the prior art rejections raised by Examiner.

Applicant has incorporated the substance of the Interview in this present Response and respectfully requests Examiner to consider the present amendments to the claims in light of the Interview of March 9, 2006.

2. Double Patenting Rejection:

Claims 19-22, 25-59 and 62-68 remain provisionally rejected under obviousness-type double patenting over claims 1-11 of co-pending U.S. Application No. 10/277,264. It is the opinion of the Examiner that although the claims are not identical, they are not patentably distinct from each other because they are both drawn to treatment of disease using immunoglobulin fusion proteins.

Applicant traverses the rejection for the reasons elaborated on in their response of October 14, 2005. Furthermore, Applicant directs Examiner's attention to the fact that the '264 application claims use of an Fc-receptor ligand and a T cell agonist. This is

distinct from use of an Ig fusion construct. In any event, Applicant notes that, according to MPEP 822.01, if the provisional double patenting rejection is the only remaining rejection in the case following entry of this amendment, the Examiner should withdraw the rejection and permit the above application to proceed to issuance.

3. Rejection of Claims Based on §112, 1st paragraph: Written Description

Claims 34-39, 41-54 56-59 and 62-65 stand rejected under §112, 1st paragraph, as failing to comply with the written description requirement. The Examiner finds the claims contain subject matter not described in the specification to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention. Applicant traverses the rejection for the reasons elaborated on in their response of October 14, 2005. Additionally, the claims as presently presented are sufficient to reasonably convey to one skilled in the art that Applicant has arrived at the claimed invention.

The claims are directed to methods of alleviating symptoms associated with specified autoimmune diseases. These autoimmune diseases are selected from the group comprising multiple sclerosis, insulin dependent diabetes and rheumatoid arthritis. Further, the claims also detail the composition to be used to alleviate said symptoms, to wit, said immunoglobulin linked to said antigen, whereby this Ig has its CDR removed and replaced with a T cell epitope. The specification discloses how the fusion construct is to be assembled. Finally, Applicant also delineates the claimed fusion protein from what is known in the art.

Thus, based on the above proffered arguments and by amending the claims to describing said antigens as those specific for autoreactive T cells associated with said autoimmune disease, rather than merely involved in said autoimmune disease, Applicant has clarified the claimed invention sufficient to overcome the Examiner's argument. Applicant has respectfully obliged Examiner's request to give some description of the

antigen in the claims and respectfully requests the withdrawal of the rejection under §112, 1st paragraph for claims 19-22, 25-59 and 62-65.

Examiner notes that while previous amendments to the claims remove some issues, problems still exist. Examiner suggests that due to the phenomenon known as epitope spreading, the claims cannot read on any autoimmune disease, as the genus would be too large and unknown. Applicant respectfully submits the claims as currently amended traverse this rejection relative to epitope spreading, as the claims are now structurally and functionally limited to involve only particular autoimmune diseases.

4. Rejection of Claims Based on § 102(b) Reference: Zanetti et al.

Examiner has rejected claims 34-57, 43-52 and 58-68 under § 102(b) as being anticipated by WO 90/09804. Examiner has noted the '804 patent ("Zanetti") teaches autoimmunity achieved through administration of Ig fusion proteins with antigens so as to induce tolerance. Further, Examiner argues that the Ig constructs as taught by Zanetti appear to have the same structure as Applicant's invention as claimed. Applicant respectfully traverses this rejection based on the response filed October 14, 2005. Additionally, Applicant's current amendments to the claims have obviated the Zanetti reference, as the structural limitations of the relevant claims no longer read on the invention described in the prior art reference. Specifically, the Ig fusion construct of the present invention, as currently amended, is a distinct structure to that described in Zanetti, as the Ig protein of the present invention must have the CDR removed and replaced with a T cell epitope specific for autoreactive T cells associated with a particular autoimmune disease. The level of specificity described in the claims now provides the necessary structural limitations which obviate the present invention from that described in the art.

Accordingly, Applicant respectfully requests Examiner to withdraw the rejection under § 102(b) based on the above arguments and concurrent amendments to the claims.

5. Rejection of Claims Based on § 102(b) Reference: De Boer et al.

Examiner has raised this new ground of rejection, finding that the claims are anticipated by De Boer et al. Based on the present amendments to the claims, Applicant respectfully requests Examiner withdraw the rejection.

In order to be a proper § 102 (b) rejection, every element of the claim must be present in the cited reference. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d, 1913, 1920 (C.A.F.C. 1989); MPEP 2131 Therefore, every element of claims 19-22, 28-29, 32-40, 43-44, 47-55, 58-59 and 62-65 must be present in De Boer to be a valid § 102(b) reference. As Examiner points out, while De Boer may teach certain methods of treating autoimmune diseases, De Boer does not “indicate that the autoantigen is to be located in the CDR3 loop of an antibody.” (Office Action of 1/10/06, pg. 11) In fact, based on the current claims, Applicant has further distinguished the present invention over De Boer by providing structural limitations in the claims. For instance, the present invention claims an Ig fusion protein which has the CDR of the Ig removed and replaced with a T cell epitope. This element is certainly not described in De Boer. Thus, based on the present amendments to the claims, Applicant respectfully requests Examiner withdraw the § 102(b) rejection.

6. Rejection of Claims Based on § 103(a): De Boer et al. in view of Zanetti et al.


Examiner rejects claims 19, 30, 31, 34, 45 and 46 under § 103(a) as being unpatentable over De Boer et al. in view of Zanetti et al.

Zanetti et al. has already been discussed. Based on the claims as presently presented, the present invention no longer reads on that claimed in Zanetti et al. Furthermore, De Boer only teaches particular methods of treating autoimmune diseases which are distinct from the present invention as currently claimed. The structural limitations in the current claims obviate both of the references. As such, Applicant respectfully requests Examiner withdraw the § 103(a) rejection and allow the application to proceed to issuance.

Applicant respectfully requests withdrawal of the above identified rejections and allowance of the present application based on Applicant's arguments and amendments. Once again, Applicant is gracious of Examiner's helpful suggestions and comments during the Interview. Applicant has attempted to use the substance of the Interview in amending the claims as presently presented. If there are any questions or comments, Applicant's attorney may be reached at the telephone number state below.

Respectfully submitted,

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